510(k) SUMMARY FOR IMRIS ONCOLOGY PACKAGE

(As required by 21 CFR 807.92)

1. GENERAL INFORMATION

Establishment:	IMRIS Inc.
Address:	100-1370 Sony Place Winnipeg, Manitoba Canada, R3T 1N5
Registration Number:	3003807210
Contact Person:	Mr. Sanjay Shah QA and Regulatory Engineer Email: sshah@imris.com Phone: 1-204-480-7070 Fax: 1-204-480-7071
Date of Summary Preparation:	July 23, 2012
Device Name / Trade name	IMRIS Oncology Package
Classification Name:	Magnetic resonance diagnostic device.
Classification Panel:	Radiology
Classification (CFR section):	21 CFR 892.1000
Class:	Class II
Product Code:	LNH

2. PREDICATE DEVICES

The IMRIS Oncology Package is substantially equivalent to the following predicate medical devices.

NAME OF THE DEVICE	510(K) NUMBER	DATE OF CLEARANCE	MANUFACTURER
MR Radiation Oncology Options	K102155	August 31, 2010	GE Medical System, LLC

3. DEVICE DESCRIPTION

The IMRIS Oncology Package provides an additional patient tabletop (MR SIMS table top) that can be used with IMRIS Neuro 1.5T / Siemens MAGNETOM 1.5T MRI scanners for radiation therapy planning. The MR SIMS table top allows patients to be imaged on a flat surface that matches the imaging patient position. The oncology package includes Head and Neck coil (HNC150) and Pelvic coil (PCC 150). Used in the IMRISneuro 1.5Tsystem/Siemens MAGNETOM 1.5 Tesla, it is indicated for use as a diagnostic imaging device to produce transverse, sagittal, coronal, and oblique images of the internal structures of the head, neck and pelvic regions. When interpreted by a trained physician, these images provide information that can be useful in determining a diagnosis. The IMRIS HNC150 and PCC150 coils can also be used as standard diagnostic head coils and pelvic coil respectively for diagnostic examinations. The Oncology package may be used with MR-conditional/ MR safe patient immobilization accessories to assist in consistent patient positions throughout multiple imaging sessions.

4. INDICATION FOR USE

The IMRIS Oncology package uses the IMRISneuro family of Intra-operative MRI systems /Siemens MAGNETOM MR systems indicated for use as a diagnostic imaging device that produce transverse, sagittal, coronal and oblique cross sectional images, spectroscopic images and / or spectra, and that display the internal structure and / or function of the entire body, including, but not limited to head, neck, and pelvis regions. Depending on the region of interest, contrast agents may be used. These images and / or spectra when interpreted by a trained physician yield information that may assist in diagnosis.

The IMRIS Oncology Package provides an additional patient tabletop for IMRIS MR systems /Siemens MAGNETOM that allows patients to be imaged on a flat surface. The flat patient surface enables IMRIS MR system/Siemens MAGNETOM to acquire images in patient positions similar to other modalities that also utilize a flat patient surface such as X-ray, CT, PET and radiation therapy.

The IMRIS MR systems/Siemens MAGNETOM MR systems with IMRIS Oncology Package may also be used with MR safe/MR conditional patient positioning and immobilization accessories to assist in obtaining consistent patient positions throughout multiple imaging sessions.

5. COMPARISION TO PREDICATE DEVICES

Characteristic	GE MR Radiation Oncology Options	IMRIS Oncology Package
FDA 510(k) #	K102155	Current Submission
Manufactured by	GE Medical Systems, LLC	IMRIS Inc.
Intended use /Indications for use	The MR Radiation Oncology Options are a patient positioning package intended for use with the GE wide bore MR Scanners. The MR Radiation Oncology Options when used with a GE wide bore MR scanner is a whole body magnetic resonance scanner designed to support high resolution,	The IMRIS Oncology package uses the IMRISneuro family of Intra-operative MRI systems/Siemens MAGNETOM MR systems indicated for use as a diagnostic imaging device that produce transverse, sagittal, coronal and oblique cross

	high signal-to-noise ratio and short scan times. The GE wide bore MR scanners with MR Radiation Oncology Options are indicated for use as a diagnostic imaging device to provide axial, sagittal, coronal, and oblique images, spectroscopic images, and/or spectra, dynamic images of the internal structures and organs of the entire body, including but not limited to head, neck, TMJ, spine, breast, heart, abdomen, pelvis joints, prostate, blood vessels, and musculoskeletal regions of the body. The images produced by the GE wide bore scanners with MR Radiation Oncology Options reflect the spatial distribution of protons (hydrogen nuclei) exhibiting magnetic resonance. These images and/or spectra when interpreted by a trained physician yield information that may assist in diagnosis. The MR Radiation Oncology Options include a removable patient table insert for GE wide bore MR scanners that allow patients to be imaged on a flat surface. The flat patient surface allows image acquisition in patient positions similar to other modalities that also use a flat patient surface such as X-Ray, CT, PET, and radiation therapy. The GE wide bore MR scanners with the MR Radiation Oncology Options may also be used with MR- compatible patient positioning and immobilization accessories to assist in obtaining consistent patient positions throughout multiple imaging sessions.	sectional images, spectroscopic images and / or spectra, and that display the internal structure and / or function of the entire body, including, but not limited to head, neck, and pelvis regions. Depending on the region of interest, contrast agents may be used. These images and / or spectra when interpreted by a trained physician yield information that may assist in diagnosis. The IMRIS Oncology Package provides an additional patient tabletop for IMRIS MR systems/Siemens MAGNETOM that allows patients to be imaged on a flat surface. The flat patient surface enables IMRIS MR system/Siemens MAGNETOM to acquire images in patient positions similar to other modalities that also utilize a flat patient surface such as X-ray, CT, PET and radiation therapy. The IMRIS MR systems/Siemens MAGNETOM MR systems with IMRIS Oncology Package may also be used with MR safe/MR conditional patient positioning and immobilization accessories to assist in obtaining consistent patient positions throughout multiple imaging sessions.
Where used	Hospital Diagnostic room	Hospital Diagnostic room
Anatomical sites	Entire body, including but not limited to head, neck, TMJ, spine, breast, heart, abdomen, pelvis joints, prostate, blood vessels, and musculoskeletal regions of the body	Entire body, including, but not limited to head, neck, and pelvis regions

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IMRIS

6. SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE: (807.92 (A) (6))

Characteristic	GE MR Radiation Oncology Options	IMRIS Oncology Package	Comparison
FDA 510(k) #	**K102155**	**Current Submission**	
MR-SIM table Top and S Frame mask adaptor			
	MR radiation oncology position insert	MR-SIM table top and S-frame adaptor	
MRI system Compatibility	GE 1.5T MRI scanners	Siemens MAGNETOM 1.5T MRI systems IMRIS 1.5T MRI systems	Same field Strength 1.5Tesla
Surface	Flat Surface	Flat Surface	Same
	Mobile patient table top with embedded high-density, posterior RF coil array	Table top with cavity allows mounting of posterior coils	Similar design
Material	Fiber glass with foam core	Acetal	Different
MRI safety	MR compatible	MR safe	Same
S-Frame and mask connecting with table top	Yes	Yes	Same
IEC 60601-1 compliance	Yes	Yes	Same
Head and Neck Coil (HNC 150)			
	GE head and neck coil (6-channel flex coil)	**IMRIS Head and neck coil (HNC150)**	**Comparison**
MRI system Compatibility	GE 1.5T MRI Scanners	Siemens 1.5T MRI scanners IMRIS 1.5T MRI system	Same field strength - 1.5T MRI Scanners
Coil Type	Receive-only six channel phased array coil	Receive-only eighteen channel phased array coil	Similar
RF Cable Interface	Interface Cable with Insulated Cable Traps	Interface Cable with Insulated Cable Traps	Same
Tune and Match	No tune, no match	No tune, no match	Same
Safety features	Active and Passive Decoupling	Active and Passive Decoupling	Same
		RF Fuse	New
Coil Enclosure Material and design	Vinyl coating closed cell foam	Vinyl coating closed cell foam	Same

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Characteristic	GE MR Radiation Oncology Options	IMRIS Oncology Package	Comparison
FDA 510(k) #	**K102155**	**Current Submission**	
	Flexible	Flexible	Same
IEC 60601-1 Compliance	Yes	Yes	Same IEC standards
Pelvic Coil (PCC 150)			
	GEM anterior array coil GEM posterior array coil	**IMRIS Pelvic coil (PCC150)**	**Comparison**
MRI system Compatibility	GE 1.5T MRI Scanners	Siemens 1.5T MRI Scanners IMRIS 1.5T MRI system	Same field strength - 1.5T MRI Scanners
Coil Type	Receive-only up to 36 channel phased array coil	Receive-only eleven channel phased array coil	Similar
System connection	The coil plugs into the MRI System	The coil plugs into the MRI System	Same
RF Cable Interface	Interface Cable with Insulated Cable Traps	Interface Cable with Insulated Cable Traps	Same
Tune and Match	No tune, no match	No tune, no match	Same
Safety features	Active and Passive Decoupling	Active and Passive Decoupling	Same
		RF Fuse	New
Coil Enclosure Material and design	Plastic, Vinyl coated closed cell foam	Plastic, Vinyl coated closed cell foam	Same
	Flexible	Flexible	Same
IEC 60601-1 Compliance	Yes	Yes	Same

7. SUMMARY OF NON-CLINICAL DATA

Design Verification and Validation Test (Bench Testing)

The IMRIS Oncology Package passed the following tests and meets product specifications. IMRIS has performed a number of V&V tests. The main tests include

- IEC 60601-1 compliance
- IEC 60601-2-33 compliance
- Clinical image comparison
- MRI compatibility test (MR image artifacts test, MR heating test),
- Surface heating (normal and single fault conditions)
- Single fault condition unplugged (passive detuning test)
- Workflow
- Loading test
- The Head and Neck coil (HNC150) and Pelvic coil (PCC 150) Image Non-Uniformity and SNR was measured and is reported in accordance with NEMA MS 9-2008 Characterization of Special Purpose Coils for Diagnostic Magnetic Resonance Images. The NEMA MS 9-2008 references the ALTERNATE MEASUREMENT PROCEDURE as described in NEMA MS 6-2008.

The oncology package is tested for electrical, mechanical, and flammability hazards. The IMRIS Oncology package complies with voluntary standards (IEC 60601-1, IEC 60601-2-33, and UL 94). The Oncology Package provided clinical images which demonstrate the clinical effectiveness of the Oncology package. The HNC 150 and PCC 150 coils are tested for MR image artifacts and surface heating test. The HNC 150 and PCC 150 coils SNR and Image non-uniformity are tested according to NEMA standards. The tests outlined above have been executed with acceptable results. Performance data demonstrate safety and effectiveness of the IMRIS Oncology Package.

8. CONCLUSION

The IMRIS Oncology Package has the same intended use and indications for use as the predicate devices. Performance data demonstrate safety and effectiveness of the IMRIS Oncology Package with the new characteristics.

The IMRIS Oncology Package verification/validation results and performance/safety standard results show that the device is safe and effective and substantially equivalent to the currently available predicate device, GE MR Radiation Oncology options.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

AUG 10 2012

Mr. Sanjay Shah
QA and Regulatory Engineer
IMRIS Inc.
100-1370 Sony Place
WINNIPEG MANITOBA R3T 1N5
CANADA

Re: K121997
Trade/Device Name: IMRIS Oncology Package
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH and MOS
Dated: July 4, 2012
Received: July 9, 2012

Dear Mr. Shah:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121997

Device Name: IMRIS Oncology Package

Indications for Use:

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Prescription Use ____x___	AND/OR	Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D)		(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety

510(k) Number K121997